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| APPLICATION NO.    | FILING DATE | FIRST NAMED INVENTOR       | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|--------------------|-------------|----------------------------|----------------------|------------------|
| 10/535,220         | 05/17/2005  | Juan Carlos Domingo Pedrol | OFICINA PONTI-256731 | 9405             |
| 21831              | 7590        | 07/06/2010                 | EXAMINER             |                  |
| Cozen O'Connor     |             |                            | ZAREK, PAUL E        |                  |
| 277 PARK AVENUE    |             |                            |                      |                  |
| 20th Floor         |             |                            | ART UNIT             | PAPER NUMBER     |
| NEW YORK, NY 10172 |             |                            | 1628                 |                  |
|                    |             |                            |                      |                  |
|                    |             |                            | NOTIFICATION DATE    | DELIVERY MODE    |
|                    |             |                            | 07/06/2010           | ELECTRONIC       |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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**ADVISORY ACTION**

1. Applicants traversed the rejections of Claims 16-22 and 25-28 and requested Examiner to enter the amendments to the claims. After careful review, Examiner is not persuaded by Applicant's arguments and the proposed amendments will not be entered.

2. Claims 16-22, and 25-28 were rejected under 35 U.S.C. 102(e) as being anticipated by Pacioretti and Babisch (US PreGrant Publication No. 2004/0106591, which claims the benefit of provisional application 60/428,246, filed on 11/22/2002).

Applicant's amendment to the claims would overcome this rejection.

3. Claims 16-22 and 25-28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Holstein, et al. (Experimental and Clinical Endocrinology and Diabetes, 2001) in view of and Connor, et al. (Annals of the New York Academy of Sciences, 1993). Examiner notes that Claim 15 was mistakenly included in the Statement of Rejection in Office Action mailed on 02/25/2010. Examiner intended the rejection to include Claims 16-22 and 25-28. Claim 15 was canceled at the time of the previous Office Action, and was not subject to examination at that time.

4. Applicant argues that lipodystrophy and hyperlipidemia are distinct disease states because the effects of the two diseases are not the same. Applicants point to Examiner's statement that hyperlipidemia is almost always associated with lipodystrophy as an indication that the two disorders are not related. Examiner does not find Applicant's arguments persuasive. Examiner points to Stedman's Medical Dictionary which teaches that lipodystrophy is a defective metabolism of fat. Hyperlipidemia is also the result of a defective metabolism of fat. Thus, treating hyperlipidemia is essentially treating

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lipodystrophy. Furthermore, *arguendo*, even if hyperlipidemia and lipodystrophy are completely unrelated, lipodystrophy is strongly associated with hyperlipidemia, such that a subject being treated for one would be suffering the other; that is, the patient populations are the same. For these reasons, Applicant's arguments are not considered persuasive. If the claimed amendments were entered, the rejection of Claims 16-22 and 25-28 would remain rejected over Holstein, et al., and Connor, et al.

5. Examiner notes that Applicant's proposed amendments raise an issue of new matter. The instant specification does not appear to provide written support administering DHA as the only active ingredient. The instant specification defines "docosahexanoic acid as active substance" to be a composition "which includes docosahexaenoic acid" (pg 3, lines 29-32, emphasis added). This definition does not preclude the presence of other active ingredients. Furthermore, Examples 1 and 2 do not demonstrate administration of DHA as the only active agent. Instead, these examples show the beneficial effects of tuna oil, which includes both DHA and EPA (see Jedwards International, Inc.). EPA is a precursor to DHA, and could be reasonably interpreted as an active substance in addition to DHA. Thus, the instant disclosure as originally filed does not appear to provide written support for the amended claims drawn to a method for the administration of a composition to a subject wherein DHA is the only active substance in the composition.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/San-ming Hui/  
Primary Examiner, Art Unit 1628